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09/786,034	04/23/2001	Gerardo Castillo	PROTEO.P07CI3	4033

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/786,034	CASTILLO ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 20-23 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment filed January 9, 2008 has been received and entered into the present application. Accordingly, prosecution has been reopened.

Pursuant to the notice dated January 22, 2008, Applicant's submission filed January 9, 2008 was non-compliant. Applicant's submission filed February 12, 2008 correcting the deficiencies enumerated in the notice dated January 22, 2008 was received and entered into the present application. Pursuant to the notice dated May 9, 2008, Applicant's submission filed February 12, 2008 was also non-compliant. Applicant's submission filed May 14, 2008 was also received and entered into the present application, but was again non-compliant pursuant to the notice dated September 30, 2008. Applicant's subsequent amendment dated October 9, 2008 has been received and entered into the present application.

Claims 20-23 are pending and under examination. Claims 20-23 are amended and claims 24-25 are cancelled.

Applicant's arguments, filed January 9, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter (New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Present claim 21 is directed to a composition comprising plant matter from a plant of the genus *Uncaria*, species *tomentosa*, dong quai and gingko biloba, in combination with one or more substances selected from the group consisting of bilberry and aloe vera, and further comprising one or more substances selected from the group consisting of chromium polynicotinate, selenium, vitamin B12 or cobalamin, folic acid, biotin, and thiamine HCl or vitamin B1.

Present claim 23 is directed to a pharmacological agent comprising a therapeutically effective amount of plant matter from a plant of the genus *Uncaria*, species *tomentosa*, dong quai and gingko biloba, in combination with a therapeutically effective amount of one or more substances selected from the group consisting of bilberry and aloe vera, and a therapeutically effective amount or one or more substances selected chromium polynicotinate, selenium, vitamin B12 or cobalamin, folic acid, biotin, thiamine HCl, or vitamin B1, the plant matter and substance and the therapeutic amount of the plant matter and substance selected for efficacy in reducing, disruption, dissolving, inhibiting, amyloid fibrils in a subject.

In particular, the specification and claims as originally filed fail to provide adequate written description for a pharmaceutical composition comprising *Uncaria*, species *tomentosa*, dong quai and gingko biloba, in combination with one or more substances selected from the group consisting of bilberry and aloe vera, and further comprising one or more substances selected from the group consisting of

chromium polynicotinate, selenium, vitamin B12 or cobalamin, folic acid, biotin, and thiamine HCl or vitamin B1 (claims 21 and 23).

Applicant fails to direct the Examiner to those portions of the instant specification that provide support for newly amended claims 21 and 23.

Relevant disclosure, however, was located at p.4, l.1-18, which states: "PTI-00703 is advantageously blended with one or more of the following ingredients for Alzheimer's disease amyloidosis, and for improved brain cognition, memory/recall optimization and the like." Applicant lists nine ingredients that may be used in combination with PTI-00703 and include gingko biloba, ginseng, gotu kola, echinacea, vitamin E, selenium, niacin or nicotinate, folic acid, vitamin B12 or cobalamin, and/or choline.

Relevant disclosure was also located at p.6, l.13-29, which states: "PTI-00703 is advantageously blended with one or more of the following ingredients for type II diabetes amyloidosis and beta cell optimization and the like." Applicant lists nine ingredients that may be used in combination with PTI-00703 and include bilberry, dong quai, aloe vera, chromium polynicotinate, selenium, vitamin B12 or cobalamin, folic acid, biotin and/or thiamine HCl or vitamin B1.

However, such disclosure of two discrete embodiments of compositions, i.e., one composition that comprises plant matter of the genus *Uncaria*, species *tomentosa*, in combination with gingko biloba, ginseng, gotu kola, echinacea, vitamin E, selenium, niacin or nicotinate, folic acid, vitamin B12 or cobalamin, and/or choline, and another composition that comprises plant matter of the genus *Uncaria*, species *tomentosa*, in combination with bilberry, dong quai, aloe vera, chromium polynicotinate, selenium, vitamin B12 or cobalamin, folic acid, biotin and/or thiamine HCl or vitamin B1, does not provide adequate written description to now claim a composition that comprises plant matter of the genus *Uncaria*, species *tomentosa*, in combination with gingko biloba (which is a combination only provided for in the context of the composition described at p.4 of the instant specification) also in combination with

dong quai, bilberry, aloe vera, chromium polynicotinate, biotin and thiamine HCl or vitamin B1 (which is a combination only provided for in the context of the composition described at p.6 of the instant specification). In other words, the disclosure of these two discrete embodiments of *Uncaria tomentosa* compositions does not now provide adequate written support to claim a composition that mixes elements of each of these two discrete compositions into another third composition that is not disclosed in the instant specification or claims as originally filed. The picking and choosing of elements from the composition described at p.4 of the instant specification with elements from the composition described at p.6 of the instant specification to arrive at a new composition that was not disclosed in the original teachings is clearly a concept that was not within Applicant's possession at the time of the instant invention. This is a clear narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear, therefore, that Applicant was not in possession of the concept of a composition comprising *Uncaria*, species *tomentosa*, dong quai and gingko biloba, in combination with one or more substances selected from the group consisting of bilberry and aloe vera, and further comprising one or more substances selected from the group consisting of chromium polynicotinate, selenium, vitamin B12 or cobalamin, folic acid, biotin, and thiamine HCl or vitamin B1 as now claimed in instant claims 21 and 23, but rather was solely in possession of the concepts of (1) a single composition comprising *Uncaria*, species *tomentosa*, in combination with gingko biloba, ginseng, gotu kola, echinacea, vitamin E, selenium, niacin or nicotinate, folic acid, vitamin B12 or cobalamin, and/or choline or (2) a single composition comprising *Uncaria*, species *tomentosa*, in combination with bilberry, dong quai, aloe vera, chromium polynicotinate, selenium, vitamin B12 or cobalamin, folic acid, biotin and/or thiamine HCl or vitamin B1.

While it is recognized that adequate written description of a limitation is not required to be stated *in haec verba* in the specification or claims as originally filed, adequate written support for all claim

limitations must arise from either an explicit or implicit suggestion by the disclosure to show that such a concept as now claimed was actually in possession of the Applicant at the time of the invention. For the reasons provided *supra*, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of pharmaceutical composition comprising *Uncaria*, species *tomentosa*, dong quai and gingko biloba, in combination with one or more substances selected from the group consisting of bilberry and aloe vera, and further comprising one or more substances selected from the group consisting of chromium polynicotinate, selenium, vitamin B12 or cobalamin, folic acid, biotin, and thiamine HCl or vitamin B1 (claims 21 and 23).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. (U.S. Patent No. 6,224,871; Issued 2001, Filed March 1998) in view of Hsia et al. (U.S. Patent No. 5,976,548; Issued 1999, filed 1997) and Zhou et al. (CN1096697, 1994; citing to STN English Abstract of the same), citing to STN Registry No. 308068-61-3 as evidence.

Hastings et al. teaches dietary compositions for promoting healthy joint function comprising a herbal blend, which comprises gingko biloba, cat's claw powder (*Uncaria tomentosa*), bilberry extract, and aloe vera extract, wherein the disclosed compositions may be administered to a subject orally. Please reference column 1, line 61-column 2, line 18; column 4, lines 50-58; column 5, lines 35-41 and Examples 1-2 at columns 4-5.

Hastings et al. fails to teach (1) the use of one or more substances selected from the group consisting of vitamin E, selenium, niacin or nicotinate, folic acid, vitamin B12 or choline (claims 20 or 22), (2) the use of dong quai (claims 21 and 23) or (3) the use of the claimed composition for reducing, disrupting, dissolving or inhibiting amyloid fibrils in a subject (claims 20 or 22).

Hsia et al. teaches nutritional supplements for the human diet for, e.g., strengthening connective and structural tissues (see col.2, l.66-col.3, l.5). Hsia et al. teaches nutritional supplements comprising ginseng, vitamin E, selenium, niacinamide, folate, vitamin B12 and choline (see Example 1, Table bridging columns 13-14).

Zhou et al. teaches a granule preparation comprising, *inter alia*, Radix Angelicae sinensis, wherein the granule preparation has effects in, *inter alia*, regulating connective tissue function (abstract).

STN Registry No. 308068-61-3 is cited for its teaching that the extract Radix Angelicae sinensis is synonymous with dong quai as used in the instant claims.

One of ordinary skill in the art would have been motivated to combine the composition of

Hastings et al. with the composition of Hsia et al. and the composition of Zhou et al. because the composition of Hastings et al. was known to promote healthy joint function and the composition of Hsia et al. was known to strengthen connective and structural tissues, tissues which are known to be integral components of human joints, and the composition of Zhou et al. was known to regulate proper connective tissue function (which, again, as stated before, is tissue known to be an integral component of human joints). In other words, each composition was known in the prior art to have joint health enhancing effects. The very fact that each was known in the art to have the same therapeutic utility raises the reasonable expectation of success that the two compositions, when combined, would have, at minimum, additive, if not synergistic, joint health promoting effects when combined.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960)."

Though the instant rejection is predicated on the finding that one of skill in the art would have been motivated to combine the elements as taught by Hastings et al. and Hsia et al. and Zhou et al. in order to arrive at a composition comprising the claimed elements for improving joint health and not specifically for the treatment of amyloidosis as instantly claimed, it is first noted that the intended use of the combined elements fails to impart any material or physical property to the presently claimed composition that would not have been present in the combination suggested by the prior art. In other words, although the art may suggest the same combination of compounds, albeit for a different use stated in the instant claims, such does not change the fact that the same combination of elements as presently claimed into a pharmaceutical composition would have been *prima facie* obvious in view of what was known in the art at the time of the invention.

In making such a combination, the skilled artisan would have necessarily considered the prior art generally available at the time of the invention regarding the claimed elements, uses of the claimed elements and reasons or suggestions to combine such elements to achieve at least additive therapeutic effects. Though the cited references suggest the combination of claimed elements for use in improving joint health, which differs from Applicant's claimed intended use for treating amyloidosis, the fact that Applicant has recognized another therapeutic advantage (i.e., treatment of amyloidosis) which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise have been obvious and the combination would have been made for another valid reason (i.e., improving joint health). Please see *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The fact that the prior art does not disclose their use in treating amyloidosis is irrelevant because the combination of such elements would have naturally commended itself to one of ordinary skill in the art at the time of the invention, regardless of the intended use of such components. Moreover, in view of the fact that products of identical composition cannot have mutually exclusive properties (see MPEP §2112), whatever effect(s) this same combination of compounds has on amyloidosis must necessarily be present in the composition suggested by the prior art, absent factual evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-23 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,264,994 in view of Hastings et al. (U.S. Patent No. 6,224,871; Issued 2001, Filed March 1998), Hsia et al. (U.S. Patent No. 5,976,548; Issued 1999, filed 1997) and Zhou et al. (CN1096697; citing to STN English Abstract of the same), citing to STN Registry No. 308068-61-3 as evidence.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending applications are not considered patentably distinct from each other because the pending claims are rendered obvious by the patented claims.

The '994 claims clearly provide for a pharmaceutical composition comprising cat's claw and, *inter alia*, gingko biloba. The patented claims also clearly teach that the composition inhibits amyloid activity (patented claim 17).

The patented claims fail to specifically teach the use of ginseng and one or more substances selected from vitamin E, selenium, niacin or nicotinate, folic acid, vitamin B12 or choline (claims 20 and 22), or the use of dong quai and one or more substances bilberry and aloe vera and one or more substances selected from chromium polynicotinate, selenium, vitamin B12 or cobalamin, folic acid, biotin, and thiamine HCl or vitamin B1 (claims 21 and 23).

Hastings et al. teaches dietary compositions for promoting healthy joint function comprising a herbal blend, which comprises gingko biloba, cat's claw powder (*Uncaria tomentosa*), bilberry extract, and aloe vera extract, wherein the disclosed compositions may be administered to a subject orally. Please reference column 1, line 61-column 2, line 18; column 4, lines 50-58; column 5, lines 35-41 and

Examples 1-2 at columns 4-5.

Hsia et al. teaches nutritional supplements for the human diet for, e.g., strengthening connective and structural tissues (see col.2, l.66-col.3, l.5). Hsia et al. teaches nutritional supplements comprising ginseng, vitamin E, selenium, niacinamide, folate, vitamin B12 and choline (see Example 1, Table bridging columns 13-14).

Zhou et al. teaches a granule preparation comprising, *inter alia*, Radix Angelicae sinensis, wherein the granule preparation has effects in, *inter alia*, regulating connective tissue function (abstract). STN Registry No. 308068-61-3 is cited for its teaching that the extract Radix Angelicae sinensis is synonymous with dong quai as used in the instant claims.

One of ordinary skill in the art would have been motivated to use the patented composition of cat's claw with gingko biloba for the purpose of promoting healthy joint function because Hastings et al. clearly teaches that a composition comprising cat's claw powder and gingko biloba is effective for this same purpose, particularly when also combined with bilberry and aloe vera as further disclosed by Hastings et al., and further combining such a composition with the composition of Hsia et al. and the composition of Zhou et al. because the composition of Hsia et al. was known to strengthen connective and structural tissues, tissues which are known to be integral components of human joints, and the composition of Zhou et al. was known to regulate proper connective tissue function (which, again, as stated before, tissue known to be an integral component of human joints). In other words, each composition was known in the prior art to have joint health enhancing effects. The very fact that each was known to have the same therapeutic utility raises the reasonable expectation of success that the compositions, when combined, would have, at minimum, additive, if not synergistic, joint health promoting effects when combined. See *In re Kerkhoven* (citation provided *supra*).

Accordingly, rejection of claims 20-23 is proper over claims 1-18 of U.S. Patent No. 6,264,994, as claiming obvious and unpatentable variants thereof.

Claims 20-23 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,939,570 in view of Hastings et al. (U.S. Patent No. 6,224,871; Issued 2001, Filed March 1998), Hsia et al. (U.S. Patent No. 5,976,548; Issued 1999, filed 1997) and Zhou et al. (CN1096697; citing to STN English Abstract of the same), citing to STN Registry No. 308068-61-3 as evidence.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending applications are not considered patentably distinct from each other because the pending claims are rendered obvious by the patented claims.

The '570 claims clearly provide for a pharmaceutical composition comprising an effective amount of an extract obtained from the plant of the genus *Uncaria*, species *tomentosa*. The patented claims also clearly teach that the composition inhibits amyloid activity (e.g., patented claim 8).

The patented claims fail to specifically teach the use of gingko biloba and ginseng and one or more substances selected from vitamin E, selenium, niacin or nicotinate, folic acid, vitamin B12 or choline (claims 20 and 22), or the use of gingko biloba and dong quai and one or more substances bilberry and aloe vera and one or more substances selected from chromium polynicotinate, selenium, vitamin B12 or cobalamin, folic acid, biotin, and thiamine HCl or vitamin B1 (claims 21 and 23).

Hastings et al. teaches dietary compositions for promoting healthy joint function comprising a herbal blend, which comprises gingko biloba, cat's claw powder (*Uncaria tomentosa*), bilberry extract, and aloe vera extract, wherein the disclosed compositions may be administered to a subject orally. Please reference column 1, line 61-column 2, line 18; column 4, lines 50-58; column 5, lines 35-41 and

Examples 1-2 at columns 4-5.

Hsia et al. teaches nutritional supplements for the human diet for, e.g., strengthening connective and structural tissues (see col.2, l.66-col.3, l.5). Hsia et al. teaches nutritional supplements comprising ginseng, vitamin E, selenium, niacinamide, folate, vitamin B12 and choline (see Example 1, Table bridging columns 13-14).

Zhou et al. teaches a granule preparation comprising, *inter alia*, Radix Angelicae sinensis, wherein the granule preparation has effects in, *inter alia*, regulating connective tissue function (abstract). STN Registry No. 308068-61-3 is cited for its teaching that the extract Radix Angelicae sinensis is synonymous with dong quai as used in the instant claims.

One of ordinary skill in the art would have been motivated to use the patented composition of the plant of the genus *Uncaria*, species *tomentosa* for the purpose of promoting healthy joint function because Hastings et al. clearly teaches that a composition comprising cat's claw powder (i.e., *Uncaria tomentosa*) is effective for this same purpose, particularly when also combined with gingko biloba, bilberry and aloe vera as further disclosed by Hastings et al., and further combining such a composition with the composition of Hsia et al. and the composition of Zhou et al. because the composition of Hsia et al. was known to strengthen connective and structural tissues, tissues which are known to be integral components of human joints, and the composition of Zhou et al. was known to regulate proper connective tissue function (which, again, as stated before, tissue known to be an integral component of human joints). In other words, each composition was known in the prior art to have joint health enhancing effects. The very fact that each was known to have the same therapeutic utility raises the reasonable expectation of success that the compositions, when combined, would have, at minimum, additive, if not synergistic, joint health promoting effects when combined. See *In re Kerkhoven* (citation provided *supra*).

Accordingly, rejection of claims 20-23 is proper over claims 1-14 of U.S. Patent No. 6,939,570, as claiming obvious and unpatentable variants thereof.

Conclusion

Rejection of claims 20-23 is proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

July 29, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614